

Exhibit B

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01- 12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

) **Hon. Patti B. Saris**
)

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Magistrate Judge**
) **Marianne B. Bowler**
)
)

**DECLARATION OF NEIL MERKL IN SUPPORT OF DEY DEFENDANTS' REPLY
IN FURTHER SUPPORT OF THEIR MOTION TO EXCLUDE FROM EVIDENCE
THE REPORTS AND TESTIMONY OF STEPHEN W. SCHONDELMAYER**

NEIL MERKL declares, pursuant to 28 U.S.C. § 1746, that:

1. I am a member of the law firm of Kelley Drye & Warren LLP, counsel to Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey"). I am admitted to practice law in the State of New York and have been admitted *pro hac vice* in this action.

2. I make this Declaration in support of Dey's Reply in Further Support of Dey's Motion *in Limine* to Exclude from Evidence the Reports and Testimony of Stephen W. Schondelmeyer.

3. The basis for my knowledge is my review of the files maintained by Kelley Drye & Warren LLP as part of its representation of Dey, including the documents attached hereto, and my own personal knowledge of the facts and circumstances set forth herein.

4. Attached hereto as Exhibit 1 is a true and correct copy of excerpts from the deposition of Stephen W. Schondelmeyer, dated September 15, 2009.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on June 24, 2010.

/s/ Neil Merkl

Neil Merkl

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on June 24, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Neil Merkl

Neil Merkl

Exhibit 1

Schondelmeyer, Pharm.D., Ph.D., Steven W. - Vol. I

September 15, 2009

Minneapolis, MN

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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS

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5 IN RE: PHARMACEUTICAL) MDL NO. 1456
6 INDUSTRY AVERAGE WHOLESALE) Master File No. 01-12257-PBS
7 PRICE LITIGATION) Subcategory Case No. 06-11337
8 -----)

9 THIS DOCUMENT RELATES TO:) Hon. Patti B. Saris
10 State of California, ex rel.)
11 Ven-A-Care v. Abbott) Tuesday, September 15, 2009
12 Laboratories, Inc., et al.)

13 - - - - - x VOLUME I

14

15 Videotaped deposition of STEPHEN W.
16 SCHONDELMEYER, PHARM.D., Ph.D., held at the Grand
17 Hotel, 615 2nd Avenue South, Minneapolis,
18 Minnesota, commenced at 9:11 a.m., the
19 proceedings being recorded stenographically by
20 Dawn Workman Bounds, Certified Shorthand Reporter
21 and Notary Public of the State of Minnesota, and
22 transcribed under her direction.

<p style="text-align: right;">Page 166</p> <p>1 actually paid and by -- that would generally be 2 paid by a substantial number of customers. 3 Q. Well, generic manufacturers, some of 4 them sell direct to independent pharmacies, true? 5 A. Some sell direct to independent 6 pharmacies. I wouldn't say that's true of all 7 generic manufacturers. 8 Q. Some do, right? 9 A. Some do. 10 Q. Some sell to distributors, right? 11 A. Some sell through wholesalers or 12 distributors. Those are different, but they're 13 similar. 14 Q. Two different things, right? 15 A. Yeah. 16 Q. So some sell to wholesalers, and some 17 sell to distributors? 18 A. Uh-huh. 19 Q. Which of those prices should it report 20 as the generally and currently paid by provider? 21 A. Well, again, they could have listed all 22 of those prices and picked the one in the middle.</p>	<p style="text-align: right;">Page 168</p> <p>1 Q. Okay. Now, this explanation you've 2 just given me as to how a manufacturer would go 3 back -- go about identifying a price generally 4 and currently paid by providers, where is that 5 written down in the regulations somewhere? 6 MS. THOMAS: Objection. 7 A. I think it's in the statutes, 8 regulations, and procedures clearly defined by 9 Medicaid over time. 10 Q. It doesn't tell them how to go about 11 figuring out which of multiple prices is the one 12 that's generally and currently paid? 13 MR. GLASER: Objection. 14 A. Again, I leave it up to the judge to 15 interpret how the regulation that states -- 16 Q. Okay. 17 A. -- generally and currently paid would 18 be implemented. But I would point out that -- 19 that the prices reported as AWP's to First 20 DataBank are not -- to the best of my knowledge, 21 not paid by anybody. So there's no possible 22 construction under which one could argue those</p>
<p style="text-align: right;">Page 167</p> <p>1 They could have listed all those prices and taken 2 the average. They could have listed all of those 3 prices and picked one that -- that more than half 4 of their purchasers paid, but the prices actually 5 reported are none of those. 6 Q. Why couldn't they pick a price at the 7 high end of their ceiling? Where does it tell 8 them they can't do that? 9 A. Well, I think that the concept 10 "generally paid" probably would preclude that. 11 Q. But there is no price generally paid? 12 A. Well, yes, there is. A price above 13 which -- you know, above which or below which a 14 price is generally paid, I think one could 15 construct that. I don't think it's difficult to 16 construct a price that's generally paid. 17 Q. But does -- 18 A. Is there some leeway about how you 19 define it? Perhaps. But -- but one could pick a 20 price generally paid, and it wouldn't be the 21 price -- the single highest price that one person 22 paid at one point in time.</p>	<p style="text-align: right;">Page 169</p> <p>1 are generally paid. 2 Q. Is there any scholarly literature, any 3 writing anywhere that defines this concept of 4 what generally and currently paid by providers 5 means in the manner that you've just described, 6 written by anyone other than you? 7 A. Very few scholars have actually 8 addressed this issue at all, you know, in any 9 context. 10 Q. So there is none? 11 MR. GLASER: Objection. 12 MS. THOMAS: Objection. 13 A. I'm not sure. I'm not aware of any. I 14 have written things related to that. I think 15 there have been a number of expert reports in 16 these cases over time that -- 17 Q. Nonlitigation. Let's stay out of 18 litigation. Okay? 19 A. Okay. 20 Q. Is there any -- 21 A. But that's been addressed heavily in 22 that context.</p>

<p style="text-align: right;">Page 170</p> <p>1 Q. I'll bet.</p> <p>2 Now, so there is no scholarly report in</p> <p>3 any peer review journal anywhere that explains</p> <p>4 what this concept of generally and currently paid</p> <p>5 by providers means in terms of what a</p> <p>6 manufacturer should report?</p> <p>7 MR. GLASER: Objection.</p> <p>8 A. Again, I believe that the regulation is</p> <p>9 what it is, and the way that will be interpreted</p> <p>10 is up to a judge and jury to evaluate.</p> <p>11 Q. So there -- there is no scholarly</p> <p>12 writing on this topic at all, is there?</p> <p>13 MR. GLASER: Objection.</p> <p>14 MS. THOMAS: Objection.</p> <p>15 A. I -- I can't answer that. I don't know</p> <p>16 for sure.</p> <p>17 Q. This concept that you have that there's</p> <p>18 this constellation of statutes and regulations</p> <p>19 that tells manufacturers what they're supposed to</p> <p>20 report, is there any scholarly article anywhere</p> <p>21 that addresses or discusses that idea --</p> <p>22 MR. GLASER: Objection.</p>	<p style="text-align: right;">Page 172</p> <p>1 wrote, other than the one that you wrote, that</p> <p>2 describes this constellation of statutes that</p> <p>3 creates an obligation on the part of</p> <p>4 manufacturers to report generally and currently</p> <p>5 paid prices?</p> <p>6 A. No, that's not true. There is an</p> <p>7 article of which I was a co-author, but there are</p> <p>8 many other co-authors that contributed in that</p> <p>9 article that -- that puts that forward. It's</p> <p>10 multiauthored, and many experts have weighed in</p> <p>11 on that.</p> <p>12 Q. What article is that?</p> <p>13 A. That's the report for the Centers for</p> <p>14 Medicare and Medicaid Services. Marian Wrobel</p> <p>15 was a coauthor, and there was an expert panel of</p> <p>16 many other parties that contributed to that.</p> <p>17 Q. Other than that document, is there</p> <p>18 anything?</p> <p>19 A. I believe there are other documents</p> <p>20 that discuss that general issue, yes.</p> <p>21 Q. What are they?</p> <p>22 A. I can't recall them sitting here today.</p>
<p style="text-align: right;">Page 171</p> <p>1 Q. -- other than the one you've written?</p> <p>2 A. Well, I believe there is the scholarly</p> <p>3 report that I, along with colleagues, prepared</p> <p>4 for the Centers for Medicare and Medicaid</p> <p>5 services addressing the issue of how can they</p> <p>6 estimate acquisition cost, and that report</p> <p>7 conducted and developed with a panel of experts</p> <p>8 who also contributed and concurred with that</p> <p>9 report.</p> <p>10 Q. So there is none, a scholarly writing</p> <p>11 --</p> <p>12 A. Yes, there is.</p> <p>13 MR. GLASER: Objection.</p> <p>14 Q. -- written by anyone other than you</p> <p>15 that explains the idea of this constellation of</p> <p>16 statutes and regulations imposing an obligation</p> <p>17 to report generally and currently paid by</p> <p>18 provider prices by manufacturers?</p> <p>19 MR. GLASER: Objection.</p> <p>20 A. Is there a question pending?</p> <p>21 Q. Yes. There is -- isn't it true there</p> <p>22 is, in fact, no article anywhere that anyone</p>	<p style="text-align: right;">Page 173</p> <p>1 Q. So you can't name another one besides</p> <p>2 that Wrobel article?</p> <p>3 MR. GLASER: Objection.</p> <p>4 A. Sitting here right now, I can't name</p> <p>5 those. I believe there are other documents</p> <p>6 describing that concept.</p> <p>7 Q. Now, that document you're talking</p> <p>8 about, isn't it a fact that one of the experts on</p> <p>9 that panel said that if not for the spread,</p> <p>10 pharmacies would be out of business?</p> <p>11 A. I believe that statement is in the</p> <p>12 document, yes.</p> <p>13 Q. So that's authoritative, too, right?</p> <p>14 MS. THOMAS: Objection.</p> <p>15 A. I believe's that's that person's</p> <p>16 opinion, and I believe that -- that to be true.</p> <p>17 It doesn't say how that spread is to be created,</p> <p>18 who has authority to create it, and who has</p> <p>19 authority to deter -- determine that as an</p> <p>20 appropriate payment mechanism.</p> <p>21 Q. And that article was written in 2004,</p> <p>22 right?</p>

<p style="text-align: right;">Page 174</p> <p>1 A. That was 2004, yes.</p> <p>2 Q. Now, prior to 2004, was there any</p> <p>3 article or writing anywhere that would -- that</p> <p>4 discussed or explained to the manufacturing</p> <p>5 industry at large this theory of the</p> <p>6 constellation of statutes and regs that require</p> <p>7 them to report generally and currently paid</p> <p>8 prices by providers as their AWP?</p> <p>9 A. I believe the federal regulations and</p> <p>10 the -- the publication of the regulation in about</p> <p>11 1987 described the price generally and currently</p> <p>12 paid, where that was. There was a discussion in</p> <p>13 the preamble of that regulation that described</p> <p>14 the intent and use of the concept by the Federal</p> <p>15 Government.</p> <p>16 MR. MERKL: Well -- well, I'll move to</p> <p>17 -- I'll reserve a motion to strike that, and</p> <p>18 we'll look at that.</p> <p>19 Q. But my question is, is there any</p> <p>20 article anywhere, any scholarly writing that</p> <p>21 explained that before 2004?</p> <p>22 MR. GLASER: Objection.</p>	<p style="text-align: right;">Page 176</p> <p>1 these cases that disagree with that, right?</p> <p>2 MR. GLASER: Objection.</p> <p>3 A. There are reports in this case that</p> <p>4 disagree with that. I don't know about the</p> <p>5 background and qualifications of the individuals.</p> <p>6 MR. MERKL: Okay. I have an exhibit</p> <p>7 that's been previously marked as Abbott 127. I'm</p> <p>8 assuming it's from the federal case.</p> <p>9 MR. GLASER: I'm sorry?</p> <p>10 MR. MERKL: Ven-A-Care, do you know</p> <p>11 what I'm talking about? There's a federal case</p> <p>12 going on between Ven-A-Care and Dey. A lot of</p> <p>13 the notices have been cross-noticed. And this</p> <p>14 exhibit I have I believe was marked in that as</p> <p>15 Abbott 127.</p> <p>16 Are you guys following any convention</p> <p>17 with marking the exhibits in this case that are</p> <p>18 pulled in and have been marked elsewhere?</p> <p>19 MR. GLASER: I don't know what</p> <p>20 conventions they're following right now.</p> <p>21 MR. MERKL: Okay. So then I'll --</p> <p>22 well, I'll just have to mark this then again as</p>
<p style="text-align: right;">Page 175</p> <p>1 A. I -- I don't -- I don't know for sure.</p> <p>2 I don't know that there is or isn't.</p> <p>3 Q. Okay. Now, this theory you have that</p> <p>4 you're supposed to report a price generally and</p> <p>5 currently paid by the providers as an AWP, can</p> <p>6 you name a scholar, other than yourself, that</p> <p>7 shares that view?</p> <p>8 MR. GLASER: Objection.</p> <p>9 A. Again, there are very few scholars who</p> <p>10 focus on this particular area. I can't think of</p> <p>11 anyone that I have discussed that issue with,</p> <p>12 particularly other scholars that -- that deal</p> <p>13 with this at this level.</p> <p>14 Q. So there isn't any?</p> <p>15 A. No, that isn't what I said. I can't</p> <p>16 think of anyone I've discussed this with to know</p> <p>17 what their opinions are. There may well be other</p> <p>18 scholars who completely agree with that.</p> <p>19 Q. But you can't tell me who they are?</p> <p>20 A. I haven't discussed that with other</p> <p>21 scholars to know; no, I haven't pursued that.</p> <p>22 Q. Okay. Now -- and there are experts in</p>	<p style="text-align: right;">Page 177</p> <p>1 Schondelmeyer -- whatever we're up to --</p> <p>2 Schondelmeyer 2.</p> <p>3 THE REPORTER: Uh-huh.</p> <p>4 (Exhibit Schondelmeyer 002 marked.)</p> <p>5 MR. GLASER: Do you have a copy,</p> <p>6 perhaps, or...</p> <p>7 Q. Do you recognize this document?</p> <p>8 A. I don't looking at it initially, no.</p> <p>9 Q. Well, isn't this -- you're sure? Take</p> <p>10 a close look. I'm startled by that.</p> <p>11 MR. GLASER: Objection.</p> <p>12 A. It appears to be a document out of, you</p> <p>13 know, somebody's reporting service --</p> <p>14 Q. Yeah, it's --</p> <p>15 A. -- Medicare and Medicaid guide.</p> <p>16 Q. Right.</p> <p>17 A. But I don't specifically recall looking</p> <p>18 at it.</p> <p>19 Q. Well, it's a CCH document, Commerce</p> <p>20 Clearinghouse?</p> <p>21 A. Yes.</p> <p>22 Q. And my question is -- well, let's take</p>